

October 31, 2003

Robert H. Roswell, M.D.
Under Secretary for Health
Department of Veterans Affairs
Washington, DC 20420

SUBJECT: NRC INSPECTION REPORT NO. (IR 030-34325/2003-015 (DNMS))

Dear Dr. Roswell:

This refers to the announced team inspection conducted on September 15 through 19, 2003, and is the first semi-annual inspection, which includes a period of review from March 17, 2003, through September 19, 2003. The purpose of the inspection was to review the activities authorized under the DVA's MML. At the conclusion of the inspection, the findings were discussed with Ms. Mari Horak, Associate Chief, Patient Care Services, and the DVA's National Health Physics Program (NHPP) staff during an exit meeting on September 19, 2003.

The NRC is implementing a program of increased oversight of the Department of Veterans Affairs (DVA) Master Materials License (MML). The increased oversight includes semi-annual inspections of the DVA's program over a 2-year period. Each inspection will include a review of DVA MML activities conducted over a 6-month period.

This inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of activities in progress, and interviews with personnel.

Based upon the inspection, no violations of NRC requirements were identified. Furthermore, the NRC found that the DVA's implementation of its MML to be adequate and consistent with NRC licensing and inspection policies and procedures.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html>.

R. Roswell

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We will gladly discuss any questions you have concerning this inspection.

Sincerely

/RA by G. Shear Acting for/

Marc L. Dapas, Director
Division of Nuclear Materials Safety

Docket No.: 030-34325
License No.: 03-23853-01VA

Enclosure: NRC Inspection Report No. 030-34325/2003-015 (DNMS))

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REGION III

Docket No.: 030-34325

License No.: 03-23853-01VA

Report No.: 030-34325/2003-015

Licensee: Department of Veteran Affairs (DVA)

Location: National Health Physics Program
Little Rock, Arkansas

Inspection Dates: September 15 - 19, 2003

Inspectors: Kevin G. Null, Senior Health Physicist and
Project Manager for DVA Master Materials License
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Approved by: John Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

**Department of Veterans Affairs Master Materials License
NRC Inspection Report No. 030-34325/2003-015**

This announced NRC team inspection was conducted to evaluate the Department of Veterans Affairs (DVA) implementation and administration of activities conducted under the Master Materials License (MML). The inspection included a review of the DVA's implementation of its centralized control program, radioactive materials permitting and inspection programs, results of Nuclear Regulatory Commission (NRC) inspections of DVA permittee facilities conducted during the review period, and a review of the National Radiation Safety Committee's (NRSC's) oversight of activities authorized by the license. Licensed activities conducted during the period of March 17, 2003, through September 19, 2003, were reviewed during this inspection.

Through discussions with DVA staff, reviews of documents, and observations of DVA staff in the performance of their duties, the NRC inspection team found the DVA's overall permitting and inspection program to be adequate to protect the health and safety of workers and the general public.

The program areas reviewed during this team inspection are summarized below:

Management Oversight

- The NRSC conducted operations in accordance with the MML, DVA's Standard Operating Procedures and NRC regulations. The NRSC was effective in performing its responsibility and providing adequate oversight of the DVA's radiation safety and regulatory compliance program.

Technical Quality of Inspections

- The DVA's inspection program was conducted in a manner that was compatible with NRC's inspection policies, procedures, and guidelines, and in accordance with the MML. The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures.

Status of Materials Inspection Program

- The inspection team concluded that the NHPP management appropriately assigned program codes and inspection due dates to its permittees, and that all inspections that were due during this review period were completed in a timely fashion.

Technical Staffing and Training

- The inspection team concluded that the DVA's MML program has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a Master Materials Licensee.

Technical Quality of Permitting Program

- Overall, the inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures and guidance. Furthermore, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

Status of Permitting Program

- The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The issuance of permitting actions by the DVA was found to be efficient and timely with no permitting actions held in backlog.

Allegation and Incident Handling Programs

- The NHPP is currently processing one allegation forwarded by the NRC to the NHPP on June 29, 2003. The DVA's allegation program was conducted in a manner that was in accordance with the MML.
- There were no reportable incidents during this review period. The DVA's program for handling incidents was conducted in a manner that was in accordance with the MML.

NRC Independent Inspections of DVA permittees

- The NRC inspected 14 DVA permittees during the review period. Two violations were identified at two separate permittee facilities. Based on the overall results of independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

1.0 Program Overview

The Department of Veterans Affairs (DVA) is authorized under NRC Master Materials License (MML) number 03-23853-01VA, to issue radioactive material permits and inspect DVA medical facilities throughout the United States. The DVA oversees approximately 118 permittees. The license was issued on March 17, 2003, and does not have an expiration date.

The DVA National Radiation Safety Committee (NRSC) has the responsibility for oversight of the MML and its permittees. The Committee has delegated the day-to-day operations to its National Health Physics Program (NHPP), which includes a Program Director and five Program Managers who are responsible for issuing permits, conducting inspections, and investigating incidents and allegations.

2.0 Management Oversight

a. Inspection Scope

The NRC inspection team reviewed the licensee's NRSC organization and management oversight activities to determine whether the Committee and its NHPP office, adequately controlled the use of licensed materials as required by the MML and NRC regulations, and in a manner that protects the public health and safety. The review included observations of NRSC meetings, discussions with cognizant licensee representatives, and a review of program documentation,

b. Observations and Findings

The team determined that the NRSC was organized as required and had implemented management oversight procedures to control the authorized use of licensed materials.

The NRSC meets quarterly and is comprised of senior DVA managers, and DVA Headquarters and field representatives. During the review period, the NRSC met twice. Based on attendance at both meetings and a review of the NRSC minutes, NRC representatives confirmed that the Committee met its minimum requirements for establishing a quorum. The NRC Project Manager and Nuclear Materials Safety and Safeguards (NMSS) Project Coordinator observed NRSC interaction with the NHPP at both meetings, and confirmed that the Committee engaged in several issues raised by the NHPP.

The NRSC delegates authority to the NHPP to manage the radiation control program and its day-to-day operations. This includes implementation of the permitting and inspection programs, incident and allegation follow-up, maintaining staffing at acceptable levels, and training of NHPP staff. The NHPP is required to implement six standard operating procedures (SOPs). The SOPs establish the essential programmatic elements for implementation of the program. The SOPs describe procedures for processing permits, conducting inspections, taking enforcement action, training inspectors, responding to incidents and managing allegations. In addition, the NHPP developed and implemented detailed internal procedures that are linked and designed to assure compliance with the SOPs.

Item 3.b of the Letter of Understanding (LOU), which is considered an adjunct to the license between the NRC and DVA, requires that the DVA update policies and procedures to reflect the most current NRC regulations. Further, Item 3.b also requires that changes or updates to NRC regulations be incorporated and distributed to staff within 90 days for immediate implementation. In October of 2002, the NRC revised 10 CFR Part 35, "Medical Use of Byproduct Material." As of September 15, 2003, the DVA SOPs had not been updated to reflect the revised 10 CFR Part 35. However, the team determined that the revised NRC regulations were distributed to NHPP staff, and licensee inspectors were aware and utilized the revised 10 CFR Part 35.

In a January 2003 document that described results of an internal audit, the NHPP documented and communicated to the NRSC the need to revise its SOPs to reflect the revised 10 CFR Part 35. The document further stated that this should be done after the NRC completed its first semi-annual inspection of the DVA's program, so that the NHPP could also incorporate additional changes into the SOPs that might be necessary as a result of the NRC inspection.

The team determined that the DVA and its permittees have implemented the revised 10 CFR Part 35. Failure to update the SOPs did not negatively impact the DVA or its permittees in implementing and complying with the revised regulations. Prior to completion of this inspection on September 19, 2003, the NHPP began to make the necessary revisions to its SOPs, and indicated they plan to request an amendment to its MML that would allow them to make non-safety related revisions to SOPs internally, without requesting approval from the NRC.

Item 5 of the LOU requires the DVA to follow NRC inspection criteria to ensure consistency between NRC and DVA inspection programs. The team determined that the DVA has implemented NRC inspection criteria. However, the team also noted that there was no link or reference in the DVA's inspection field notes or its intranet web site, to NRC inspection criteria/procedures. As of September 19, 2003, the NHPP addressed this issue by updating its web site and IPs to include references to relevant NRC IPs and inspection criteria.

c. Conclusion

Overall, the inspection team found that the NRSC conducted operations in accordance with the MML, DVA's SOPs and NRC regulations. The NRSC was effective in performing its responsibility and providing adequate oversight of the DVA's radiation safety and regulatory compliance program.

3.0 Technical Quality of Inspections

a. Inspection Scope

The NRC inspection team reviewed inspection plans, inspection reports, enforcement documents and correspondence associated with inspections conducted by the NHPP during the review period to determine if NHPP inspections were consistent and in conformity with NRC inspection procedures. In addition, the team interviewed NHPP inspectors to evaluate their process in preparing for inspections, including study of the permit (or previous NRC license), licensing related documents, and regulatory requirements. The team also evaluated their use of supporting documents (e.g.,

permitting files, regulatory guides, and regulations), and the equipment and instrumentation provided to the inspectors for performing inspections.

b. Observations and Findings

The team determined that NHPP inspectors properly prepared for inspections, and were provided with the necessary tools for performing their inspections.

The NHPP staff performed 10 inspections of permittees and one inspection of a non-permittee during the review period. The inspections were routine inspections as well as reactive, covering different types of permittees, including Medical Broad, Medical Institutions QMP (Quality Management Program) not required, Medical Institutions QMP required, and Research and Development. The team determined that for all inspections performed, the inspectors generated inspection plans which were reviewed and approved by the NHPP Director. The inspection team determined that inspection plans used, followed the typical areas of applicable NRC Inspection Procedures as described in the NRC Inspection Manual Chapter 2800, Materials Inspection Program.

The inspection team determined that NHPP inspection reports documented areas reviewed by the inspectors and that inspection plans were followed to perform the inspections. The inspection team noted that inspection findings were based on health and safety matters, and were well-founded and properly documented. The team found that inspection reports were complete, and that the review of inspection findings performed by the NHPP Director was in accordance with NRC practices, and completed in a timely manner. The team also noted that each NHPP inspector was evaluated during an accompaniment over the review period by the NHPP Director.

Each NHPP inspector was also accompanied by a NRC inspector during the review period. The purpose of the accompaniment was to evaluate the technical quality of inspections being performed by NHPP inspection staff. In addition, the NRC Region III Project Manager accompanied the NHPP Director while the director observed an inspection being performed by one of his inspectors.

c. Conclusion

The inspection team concluded that the licensee's inspection program was conducted in a manner that was compatible with NRC's inspection policies, procedures, and guidelines. The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures.

4.0 Status of Materials Inspection Program

a. Inspection Scope

The NRC inspection team reviewed the licensee's program for assigning inspection frequencies to permittees, and its timeliness in completing inspections based on inspection due dates. The team interviewed NHPP inspectors and management, and compared the licensee's inspection due dates posted in its tracking system against the actual dates that inspections were completed.

b. Observations and Findings

The NHPP adopted the NRC's inspection frequencies for its permittees when the MML was issued on March 17, 2003. The team noted that the NHPP adjusted and reassigned program codes to 17 permittees. This resulted in changes to inspection frequencies for each of these permitted facilities. The majority of these changes resulted in new inspection frequencies that were more conservative. For example, some permittees were reclassified from a standard medical program (program code 2120) to a research and development Type A broad scope program (program code 3610). Some permittees inspection frequencies were modified based on the NRC's revision to its inspection frequency program. All inspections were completed by required due dates and there were no overdue inspections.

c. Conclusion

The inspection team concluded that the NHPP management appropriately assigned program codes and inspection due dates to its permittees, and that all inspections that were due during this review period were completed in a timely fashion.

5.0 Technical Staffing and Training

a. Inspection Scope

The NRC inspection team reviewed the licensee's radioactive materials program staffing level and turnover, as well as the technical qualifications and training history of the NHPP staff. In evaluating these elements, the team examined the DVA's response to the NRC's questionnaire relative to this indicator, interviewed program management staff, and reviewed the DVA training program, job position requirements, and casework related to licensing, compliance and inspection. The team also conducted accompaniments of qualified NHPP inspectors.

b. Observations and Findings

The NHPP personnel are assigned as headquarters-level staff reporting to the Chief of Patient Care Services. The NHPP is staffed with a Director, five Program Managers, and administrative personnel. The Director provides a two-way vertical conduit for interaction and communication of information between the NRSC and Program Managers, and has the sole signature authority for permit issuance. There has been no staffing turnover since the issuance of the MML on March 17, 2003.

The program has built in flexibility as the Director and Program Managers are all qualified to perform both permitting reviews and inspections. Additionally, each Program Manager is expected to develop expertise in specific assigned areas. For instance, there are specialists in the areas of decommissioning and high dose-rate remote brachytherapy. The administrative support staff are also cross-trained to perform all administrative functions.

The NHPP developed a written training program for its technical staff based on the requirements specified in NRC Inspection Manual Chapter 1246. The program includes qualification journals and oral qualification boards. All Program Managers have completed the NRC Fundamentals of Inspection and Licensing Practice and Procedures courses, as well as some of the other NRC and equivalent NRSC approved courses.

The NHPP schedules its Program Managers for other core NRC courses as the space becomes available. The NHPP has successfully balanced the acquisition of training with maintaining the permitting and inspection workload, while successfully implementing a centralized control program.

The team reviewed the formal education and experience of the NHPP Director and technical staff. They all have an undergraduate degree in an applicable discipline, with most possessing a Master's degree, and one manager holding a Doctoral degree. All have served as a Radiation Safety Officer (RSO) for a broad scope material license and have 15-25 years of health physics experience.

c. Conclusion

The inspection team concluded that the DVA's MML program has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a Master Materials Licensee.

6.0 Technical Quality of Permitting Program

a. Inspection Scope

The NRC inspection team reviewed 15 DVA permitting actions completed by the NHPP Program Managers and interviewed the staff to determine whether the DVA's permitting program was consistent with NRC licensing policies and procedures. Permitting actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permit actions. Casework was also evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The casework was selected to provide a representative sample of permitting actions that were processed for DVA permittees during the review period. The sampling included the following types of permits: medical broadscope, limited medical institution, and research and development broadscopes. The types of permitting actions selected for evaluation included 8 amendments to existing permits, 5 renewals, and 2 terminations. No new permit requests or actions submitted with potential significant environmental impact or complex decommissioning activities were processed during the review period.

b. Observations and Findings

The casework evaluation indicated that the NHPP staff follows appropriate NRC NUREGs, policies, procedures and directives during the review process to ensure that the submitted information supports the permittee's request. The team found the technical reviews (checklists) used for each type of program to be complete and

comprehensive. As a result, the team noted significant consistency between the reviewers. Deficiencies identified were addressed in letters and documented telephone conversations. The team also determined that the letters and telephone conversation records contained appropriate regulatory language, were detailed, and provided the necessary information to support the action. All permitting actions were reviewed and signed by the NHPP Director and forwarded to NRC on a quarterly basis.

c. Conclusion

Overall, the inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures and guidance. Furthermore, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

7.0 Status of Permitting Program

a. Inspection Scope

The NRC inspection team reviewed the licensee's permitting process to verify that permitting actions were handled and processed as described in the license. The team also evaluated the effectiveness of the licensee's tracking system.

b. Observations and Findings

The NHPP is responsible for approximately 118 medical and medical/research permittees. Five regional NHPP Program Managers conducted inspections and processed permitting actions. Since the inception of the MML on March 17, 2003, NHPP has processed 49 permitting actions. The NHPP averaged 10 days to issue its permitting actions, which included both renewals and amendments. The NHPP did not issue any new permits during this review period.

The NHPP enters permitting actions it receives from permittees into its Records Tracking Management System (RTMS). The RTMS is a system that is utilized to track casework and is maintained in an electronic, centrally controlled file database. The actions are entered into the database, scanned and electronically filed and archived. After processing by the Administrative Officer, the permit requests are assigned and electronically provided to a Program Manager's office for review.

The RTMS also provides the NHPP staff access to licensing guidance documents (e.g., permit files, guidance criteria, inspection history, etc.). In addition, the tracking system provides NHPP staff with the capability to follow the status of any permitting action from start to completion. The system also assures that information will be readily retrievable for staff use and program assessments.

c. Conclusion

The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The issuance of permitting actions by the DVA was found to be efficient and timely with no permitting actions held in backlog.

8.0 Allegation and Incident Handling Programs

a. Inspection Scope

The NRC inspection team reviewed the DVA's program for handling allegations and incidents. This included a review of all incidents and allegations to determine applicability to NRC reporting requirements, and the effectiveness of handling both incidents and allegations by the NHPP, and communications between the NHPP and NRSC. The team evaluated four cases maintained in the licensee's event/incident file for reportability requirements, and interviewed key licensee personnel involved with each case. These cases involved disposal of radioactive materials to two landfills, an unusually high film badge reading assigned to a permittee staff member, and possession of byproduct material by an unlicensed VA medical center.

b. Observations and Findings

The inspection team determined that there were no reportable events for this inspection period.

One landfill disposal event involved material from a facility in Florida that could not be traced to a VA permittee, and the other event was determined not to be reportable by the DVA, and by the NRC, based on the results of an independent inspection. A special inspection of the high film badge reading conducted by the NHPP, with accompaniment by an NRC inspector, determined that the exposure was to the badge and not the employee. Regarding the unlicensed VA facility, the NHPP discovered that Bath VA Medical Center, New York, was in possession of microcurie amounts of carbon-14 and calcium-45. The material was transferred to a licensed VA facility authorized to possess carbon-14 and calcium-45. The DVA is conducting an investigation to review the circumstances surrounding this case. The NRC will continue to follow the DVA's investigation into this issue.

The NHPP is currently reviewing one allegation. The allegation was initially received by the NRC and forwarded to the NHPP in late June of 2003. The NHPP initiated its investigation in mid-July. Information concerning the allegation was forwarded in early July to the NRSC Chairman by the Director of the NHPP. However, the team determined that as of September 15, 2003, the allegation had not been communicated to the NRSC membership. Furthermore, it was not included as an agenda item for discussion at the most recent NRSC quarterly meeting held on July 31, 2003.

The licensee's Standard Operating Procedure (SOP) 06, "NHPP Allegation Management Program," requires direct involvement of, and interaction with, the NRSC in the receipt and handling of allegations. Based on interviews of NHPP staff, it appears that although the NRSC Chairman was notified of the allegation, neither the NHPP nor the NRSC Chairman informed the NRSC membership of the allegation. The inspection team determined that this lack of communication was an oversight on the part of the NHPP and NRSC Chairman.

Prior to completion of this inspection on September 19, 2003, the NHPP stated that the allegation would be presented to the NRSC during the October 30, 2003, committee meeting.

c. Conclusion

The NHPP is currently processing one allegation forwarded by the NRC to the NHPP on June 29, 2003. The inspection team concluded that despite the lapse in communication with the NRSC membership regarding this allegation, the DVA's allegation program was conducted in a manner that was in accordance with the MML.

There were no reportable incidents during this review period. The DVA's program for handling incidents was conducted in a manner that was in accordance with the MML.

9.0 NRC Independent Inspections of DVA Permittees

a. Inspection Scope

During the period of this inspection, the NRC performed independent inspections of DVA permittees to assess the adequacy of permitted radiation safety programs and compliance with NRC regulations and the MML. The NRSC's corrective actions, through the NHPP, were reviewed for completeness, timeliness and effectiveness.

b. Observations and Findings

During the period from March 17 through September 19, 2003, the NRC conducted 14 independent inspections of DVA permittees. The NRC focused its inspections on the higher risk programs, i.e., priority 1 and 2 programs, e.g., medical broad scope programs, etc. The NRC did not identify any violations in 12 of the 14 inspections that were conducted. Two inspections identified violations associated with security and control of radioactive material (ref. IR 03034325/2003-005 (DNMS) and IR 03034325/2003-004 (DNMS)).

The team reviewed the licensee's immediate and long term corrective actions for the violations and found them to be sufficient to address the issues and prevent recurrence.

c. Conclusion

Based on the overall results of independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

10.0 Exit Meeting

An exit meeting was held with DVA representatives on September 19, 2003. The overall scope and findings of the inspection were discussed. The DVA participants did not identify any information as being proprietary in nature.

LIST OF PERSONS CONTACTED

Licensee Personnel

#M. Horak, Associate Chief, Patient Care Services

*E. Leidholt, Ph.D., Program Manager, NHPP Southwest Office

K. Mayo, Information Technologist, NHPP Headquarters

*L. McGuire, Director, NHPP Headquarters

J. McNew, Program Support Assistant, NHPP Headquarters

*L. Offutt, Administrative Officer, NHPP Headquarters
*M. Simmons, Program Manager, NHPP Northwest Office
*G. Williams, Program Manager, NHPP Headquarters
#J. Wissing, Program Manager, NHPP Central Office
*P. Yurko, Program Manager, NHPP Eastern Office

NRC Personnel

*U. Bhachu, Mechanical Engineer, NMSS/IMNS
*J. Díaz Vélez, Health Physicist, Region II
*J. Madera, Chief, Materials Licensing Branch, Region III
*K. Null, Sr. Health Physicist, Region III
*T. Simmons, Health Physicist, Region III

*Attended September 19, 2003, exit meeting

#Attended September 19, 2003, exit meeting by telephone

In addition, numerous permittee staff were interviewed during the independent inspections conducted by the NRC during the review period March 17 through September 15, 2003.

LIST OF ACRONYMS, ABBREVIATIONS

CFR	Code of Federal Regulations
DVA	Department of Veterans Affairs
IMNS	Industrial and Medical Nuclear Safety
IP	Inspection Procedures
LOU	Letter of Understanding
MML	Master Materials License
NHPP	National Health Physics Program
NMSS	Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
QMP	Quality Management Program
RSO	Radiation Safety Officer
RTMS	Records Tracking Management System
SOP	Standard Operating Procedure
VA	Veterans Affairs